AliveCor® Mobile ECG

User Manual for iOS

NOTE: For the current information on your product please visit http://www.alivecor.com/user-manual

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1. PRODUCT DESCRIPTION

The AliveCor® Mobile ECG (Mobile ECG) is a mobile, clinical-quality electrocardiogram (ECG) recorder. The duration of the recording established by the AliveECG app with a default setting of 30 seconds and a maximum time of 5 minutes. The software application can store thousands of recordings on your smartphone or tablet and these recordings are also accessible to authorized users on AliveCor, Inc. (AliveCor) servers (www.alivecor.com).

Patients with known or suspected heart conditions and health conscious individuals can use the AliveCor Mobile ECG to record an ECG daily or whenever they are feeling symptoms and share their recordings with their physician. Medical professionals can use the AliveCor Mobile ECG to quickly assess rate and rhythm, screen for arrhythmias, and remotely monitor and manage patients who use the AliveCor Mobile ECG.

The device consists of three components:

1. The Mobile ECG, which attaches to your compatible smartphone or tablet and has electrodes to transmit ECG rhythms to the smartphone or tablet.
2. The *AliveECG* mobile application (*AliveECG* app) is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. A user-supplied compatible smartphone or tablet.

CAUTION: The AliveCor Mobile ECG has features that are only available to those users who are under the care of a physician. These features are available to prescription users only.

The Mobile ECG enables users to:

- Collect and store single-channel ECG recordings using the smartphone or tablet.
- Edit user information data associated with the recording.
- Wirelessly transmit ECG recordings to the AliveCor server.
- Access ECG recordings stored on the AliveCor server.
- Print or save the recording in PDF format.
- Request professional clinical interpretation and analysis of your ECG recordings.

After a user has created an account on the *AliveECG* app and received an ECG analysis, the Mobile ECG enables a user to:

- View ECG recordings real-time and after the recording.
- View the output of the Atrial Fibrillation, Normal, and Interference Detectors.

1.1. Indications for Use

The AliveCor Mobile ECG is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Mobile ECG also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Mobile ECG is intended for use by healthcare professionals, individuals with known or suspected heart conditions and health conscious individuals. The device has not been tested for and it is not intended for pediatric use.

1.2. Contraindications

There are no known contraindications for the Mobile ECG, although care should be taken when considering using the device according to the warnings and precautions below.

2. GENERAL SAFETY PRECAUTIONS

- The device should not be used near water, or in a wet environment.
- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Signal quality may degrade by detecting signals from other ultrasonic acoustic sources. Do not use the device in close vicinity to other equipment emitting ultrasonic acoustics such as espresso machines, some ventilation systems or another AliveCor Mobile ECG.
- Power adapters may degrade signal detection. Do not use the Mobile ECG while charging the smartphone or tablet.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful recording may not be possible.
- Some children and adults with very sensitive auditory ability may hear a high-pitched hum or buzz emitting from the device when activated. This is due to normal device function.

3. STORAGE, HANDLING AND MAINTENANCE

Do not store the unit in:

- Locations exposed to direct sunlight,
- Locations subject to high temperatures and high humidity,
- Wet or damp locations where water may get on the unit,
- Dusty locations,
- Near fires or open flames,
- Locations exposed to strong vibration, or
- Locations exposed to strong electromagnetic fields.

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using an alcohol-based sanitizer before each use.
- To prevent potential cross-infection of diseases between users, clean the device using alcohol prior to each use.

4. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.
- This device records heart rate and heart rhythm only.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional.
- Users should always consult their physician if they notice changes in their health.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- The device has not been tested for use on infants weighing less than 10kg. AliveCor does not recommend using on humans less than 10kg.
- It is not recommended to place a mobile phone directly next to a pacemaker on the chest.
- Do not use this device with a defibrillator.
- AliveCor does not recommend using on individuals with a cardiac pacemaker, ICDs or other implanted electronic devices.
- Do not attempt ECG data acquisition while there is an external microphone plugged in to the smartphone or tablet.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- The heart rate is based on the heart rhythm; therefore the rate is only valid if there is a valid rhythm (QRS complex visible).
- The Interference Detector may incorrectly identify ventricular flutter, ventricular bigeminy and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Interference Detector in your Settings.
- AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an ECG as normal. You should notify your doctor of a possible change in your health.

5. SET UP THE MOBILE ECG AND TAKE THE FIRST ECG RECORDING

5.1. Decide which smartphone or tablet to use

Your Mobile ECG is compatible with all of the smartphones and tablets listed on AliveCor's website: http://www.alivecor.com/compatibility, including:

- iPhone 4/4s, 5/5s, 5c, 6, 6 Plus
- iPad Air, iPad Mini
- iPod Touch 5G

The AliveECG App is compatible with iOS versions 6.0 – 8.2

You can use the Mobile ECG on all compatible smartphones or tablets as listed on the Compatibility Chart.

The Mobile ECG for iPhone 5/5s and iPhone 6 can also be used on all compatible smartphones or tablets by removing the oval-shaped Mobile ECG from its case:

1. If the Mobile ECG is currently attached to an iPhone 5/5s, remove it and itscase from your iPhone 5/5s (press gently on the phone camera through the case cutout and peel back from that corner of the Mobile ECG).
2. Face the electrodes of the Mobile ECG away from you.
3. AC-007: Gently push the left side of the Mobile ECG toward you while at the same time gently pulling the left edge of the case away from the device itself.
4. The Mobile ECG should then "pop out" of its case.

5.2. Unpack the Mobile ECG

1. Remove the Mobile ECG from the box.
2. Choose Mobile ECG placement.
   a) For Mobile ECG cases, place the Mobile ECG on your phone as you would any standard phone case.
   b) The Mobile ECG can be attached directly to the smartphone or tablet or to the case of your choosing (the surface should be smooth and flat).
      a. AC-001 - AC-007: With the AliveCor logo right side up, the top of the smartphone or tablet should be on the right.
      b. AC-009: With the AliveCor logo right side up, the top of the smartphone or tablet should be at the top.
   c) For use with an iPad, AliveCor does not recommend attaching the Mobile ECG to your tablet. Instead, rest the Mobile ECG in both hands or place it on a flat surface less than one foot away from the iPad to record ECGs.

Caution: The Mobile ECG must be less than 1 foot from the smartphone or tablet to ensure communication between devices.

5.3. Download the *AliveECG* App

1. Using your smartphone or tablet, search for *AliveECG* in the App Store.
2. Download and install the *AliveECG* app.

5.4. Set up an AliveCor Account

You will use your AliveCor account to access, print and save your ECG recordings stored on the *AliveECG* app and the AliveCor server. Follow the instructions presented when you open the *AliveECG* app for the first time. You can go back later and change your information if necessary. Signing up for an AliveCor account also enables you to send an ECG for analysis. ECG analysis can be used any time you want a medical professional to interpret your ECG recording and is required if you would like to view your recordings or utilize AliveCor's Detectors.

6. RECORD ECG RHYTHMS USING THE MOBILE ECG

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your smartphone or tablet, launch the *AliveECG* app.

Rest two or more fingers (it doesn't matter which fingers) on the Mobile ECG; your right hand should contact the electrode closest to the bottom of the smartphone or tablet, and your left hand should contact the electrode closest to the top of the smartphone or tablet. This is a Lead I ECG.

You may also choose from two other placements:

- For a Lead II ECG, the left knee should contact the electrode closer to the top of the smartphone or tablet and the right hand should contact the electrode closer to the bottom of the smartphone or tablet.
- For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. The bottom of the smartphone or tablet should be pointing towards the center of the body.

NOTE: You will not be able to view your recordings or utilize any of AliveCor's Detectors until you are under the care of a physician. To gain access to these features, you must create an account on the *AliveECG* app. Your first recording will then be automatically sent for a free analysis by a cardiologist. Once you have received the ECG analysis, you will have access to view that recording and subsequent recordings.

After your display is unlocked, you may swipe your finger across the screen to scroll through each ECG recording. Additionally you can add notes about the recording:

- Tap the "Annotate" icon in the upper right corner to add notes:
  - Medical Professional – Add patient details such as Patient ID, Name, etc.
  - Individual User – Add symptoms and activities
- Tap "Save" to return to the review screen. This information will automatically synchronize with the AliveCor server.

NOTES:

- The Mobile ECG does not require a Wi-Fi or mobile connection to record an ECG and save it to the smartphone or tablet, however it does require one of these to: sync automatically with the AliveCor server, email, or print directly from the *AliveECG* app. If you do not have a Wi-Fi or mobile connection at the time of the ECG recording, you can email or print the data later when you have such a connection and the sync will happen automatically at that time.
- The Mobile ECG can be used up to a distance of 30 cm (1 ft.) from the smartphone or tablet. Using the Mobile ECG at a distance greater than 30 cm (1 ft.) may lead to communication issues between the devices and your recording may not be successful.
- In order to reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.
- You must maintain contact with the electrodes for at least 10 seconds for the recording to be saved. If you remove contact after 10 seconds, but before the selected recording duration is complete, the ECG will be saved and you will be able to review it.
- The recording must be at least 30 seconds long in order for the Detectors to work.

7. ONCE THE RECORDING IS FINISHED

- Immediately after recording, you may select symptoms and activities on the next screen. You can also enter personalized symptoms and activities, or comments and notes. After making your choices tap “Save” to move on to the ECG History screen.
- If this is a guest recording, immediately after recording, scroll down to the bottom of the symptoms and activities screen and tap “Not [Your Name]?" You can then enter the guest’s name and email them more information about AliveCor.
- When you are finished recording an ECG and enter symptoms and activities, you can review the ECG through ECG History or go to Insights and view the trending of your ECGs, heart rate, symptoms and activities, and medications.

8. SETTINGS AND ADJUSTMENTS

8.1. Recording Adjustments

- **Paper Speed and Gain (or Zoom)**. Changes to the paper speed and gain can be performed by medical professionals only. These changes are made while viewing in landscape orientation by tapping the text in the lower left portion of the review screen and selecting the preferred setting. The scaling will adjust on the screen automatically. Also, these changes can be made prior to the recording. Alternately, you can pinch and zoom when viewing the recording as a PDF (tap the box with the arrow in the lower left corner and tap “PDF”.
- **Enhanced and Original Filter.** The Enhanced Filter suppresses noise in the ECG. The filter can be toggled by tapping the text labeled “Enhanced Filter” or “Original Filter”.
- **Invert the ECG recording**. In the event that the Mobile ECG was oriented improperly while the ECG rhythms were recorded, it may appear inverted. To correct the orientation, tap on the center of the review screen, and then tap “Invert”.

8.2. Adjustable Settings

To access the Settings screen in the *AliveECG* app, tap on the "More" icon at the lower right and then tap on "Settings".

- **Duration**. Recording Duration is the maximum length of time the *AliveECG* app will record a single ECG recording. For example, if the recording duration is set to 30 seconds, the *AliveECG* app will automatically stop recording after 30 seconds of data has been collected.
- **Mains Filter**. The Mains Filter removes any mains interference from the ECG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- **Paper Size**. Paper Size of the PDF report can be changed to accommodate Letter and A4 paper sizes.
- **Reminders**. Reminders allow the ECG analysis reminder to be turned on or off. It also allows you to turn on or off the ECG reminder, set the frequency, and time for the reminder. You can also turn the AF Detector on or off, and modify your medication reminders.
- **Mode**. Tap to modify device transmission settings. Normal mode is recommended for most users. If your facility or location limits wireless communication, the Airplane/ICU setting may be selected.

9. EMAIL, PRINT OR DELETE RECORDINGS

NOTE: If you are not enrolled in Alivecor's ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

You may email/print recordings from either the *AliveECG* app or your account on the server (www.alivecor.com).

To email a recording from the *AliveECG* app, you must have an email account set up on your smartphone or tablet. If you need assistance setting up an email account or troubleshooting your email account, please contact your smartphone or tablet provider for assistance.

1. After selecting the desired ECG recording from ECG History, tap the square with the arrow in the upper right.
2. Tap Email. The PDF version of the ECG recording will then be attached to a new email in whatever email account you have set up on your smartphone or tablet.

To email a recording from the server:

1. Go to www.alivecor.com.
2. Click on "SIGN IN" in the upper right corner and enter your email address and password.
3. Select the desired recording by clicking on the appropriate "VIEW ECG" button on the right.
4. Email from your computer as you would any PDF.

To print a recording from the *AliveECG* app, you must have an AirPrint compatible printer set up on your smartphone or tablet. If you need assistance setting up an AirPrint compatible printer or troubleshooting your AirPrint compatible printer, please contact your smartphone or tablet provider for assistance.

1. After selecting the desired ECG recording from ECG History, tap the square with the arrow in the upper right.
2. Tap Print.

To print a recording from the server:

1. Go to www.alivecor.com.
2. Click on "SIGN IN" in the upper right corner and enter your email address and password.
3. Select the desired recording by clicking on the appropriate "VIEW ECG" button on the right.
4. Print from your computer as you would any PDF.

To delete a recording:

1. Go to ECG History.
2. Tap "Edit" in the upper right, or swipe a recording from right to left and select "Delete".

Deleting a recording from the *AliveECG* app also deletes it from the server. Deleted recordings cannot be retrieved.

10. VIEW PREVIOUSLY RECORDED ECG RECORDINGS ON YOUR SMARTPHONE OR TABLET

NOTE: If you are not enrolled in Alivecor's ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

- Launch the *AliveECG* app.
- Tap History in the menu at the bottom to see a list of all ECG recordings on your smartphone or tablet (excluding any previously deleted).
- Tap the ECG recording you wish to view.

11. VIEW AN ECG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are not enrolled in Alivecor's ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

- On your web browser, go to www.alivecor.com and click on "SIGN IN".
- Enter your email address and the password you created when you set up your AliveCor account. Click "Sign In".
- The ECG recordings you collected were automatically synced to the AliveCor server and will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file and can also be viewed in HTML. Click on the "VIEW ECG" button.
- Click the back button in your browser to return to your AliveCor account homepage.

12. ECG ANALYSIS

The *AliveECG* app includes the ability to request professional clinical interpretation and analysis of your ECG recordings. Due to telemedicine restrictions, your location may restrict your ability to use this service. AliveCor does not know your location; it is your responsibility to ensure this service is legal according to your local telemedicine laws. This service is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

To have a recording analyzed:

1. Tap the "ANALYSIS" button that appears in the lower left of a new recording or when you view recordings from your history.
2. Select the type of service desired.
3. If you haven't already entered your name, date of birth and gender, you will be prompted to enter these details.
4. Tap "Add new card".
5. Enter credit card information.
6. Tap "Submit New Card".
7. Confirm and tap "PURCHASE" to proceed.

You will receive a notification once your analysis has been returned.

NOTE: The "Analysis" option is only visible if the analysis service is available in your country.

To view an ECG analysis that has been returned:

1. Tap "History".
2. Tap the desired report
3. Tap "Analysis" in the lower left.

13. DETECTORS (ATRIAL FIBRILLATION, NORMAL, INTERFERENCE)

NOTE: If you are not enrolled in Alivecor's ECG Analysis service, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician

NOTE: Your ECG must be at least 30 seconds long to use the Atrial Fibrillation and Normal Detectors. If an ECG is recorded that is less than 30 seconds, neither the Atrial Fibrillation nor the Normal Detector will display a result.

Atrial Fibrillation Detector

The Atrial Fibrillation (AF) Detector in the *AliveECG* app detects atrial Fibrillation in an ECG tracing. After you take an ECG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis, it is only a potential finding. You should contact your physician to review any ECG recording in which atrial fibrillation was detected, or send it to ECG Analysis. If you are experiencing any symptoms or concerns please contact a medical professional.

The AF Detector monitors for atrial fibrillation (AF) only. It will not detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.

The AF Detector only monitors for AF while you are taking a recording. It does not continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

Normal Detector

The Normal Detector in the AliveECG app notifies you when a recording is “normal”. This means that the heart rate is between 50 and 100 beats per minute, there are no or very few abnormal beats, and the shape, timing and duration of each beat is considered normal. It is important to remember that there is a wide range of normal variability among different individuals. Changes in the shape or timing of an ECG might be normal for a single individual, but since the AliveCor Mobile ECG is used by a large and diverse population, the Normal Detector has been designed to be conservative with what it detects as normal.

If you have been diagnosed with a condition that affects the shape of your ECG (e.g., intraventricular conduction delay, left or right bundle branch block, Wolff-Parkinson-White Syndrome, etc.), experience a large number of premature ventricular or atrial contractions (PVC and PAC), are experiencing an arrhythmia, or took a poor quality recording it is unlikely that you will be notified that your ECG is normal.

It is also important to note that the Normal Detector looks at the entire signal before determining if it can be declared to be normal. If you experience a small number of PACs or PVCs in a recording of otherwise normal beats in normal rhythm, the Normal Detector will likely declare this recording to be normal.

WARNING: AliveCor cannot guarantee that you are not experiencing an arrhythmia or other health condition when labeling an ECG as normal. You should notify your doctor of a possible change in your health.

Inteference Detector

The Interference Detector in the AliveECG app determines whether a recording can be accurately interpreted or not. After you take an ECG, if interference is detected you will be notified within the app that your recording is “Unreadable” and given some suggestions for acquiring the best quality ECG recording. You subsequently have the option to Save the recording, or Try Again. If the recording can be analyzed, the AF and Normal Detectors will run on the ECG and inform you as described above.

WARNING: The Interference Detector may incorrectly identify ventricular flutter, ventricular bigeminy and ventricular trigeminy as unreadable. If you have been diagnosed with one or more of these arrhythmias, we recommend turning off the Interference Detector in your Settings.

13.1. What is Atrial Fibrillation?

The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In this case, disorganized electrical impulses that originate in the atria and pulmonary veins initiate the electrical activity in the conduction system of the heart. This causes what are commonly termed as “irregularly irregular” heart beats.

When a heart is in atrial fibrillation, its two upper chambers, the right and left atria essentially quiver, instead of beating efficiently. This does not allow for complete emptying of the atria and thus, blood may become stagnant and create blood clots. This can lead to major problems, namely, strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.

Approximately 15 percent of strokes occur in people with atrial fibrillation. As age increases in a population, so too does the incidence of atrial fibrillation, which peaks at about 3-5% in people over the age of 65.

The most common presenting symptoms of atrial fibrillation are palpitations, dizziness, fast pulse rate, irregularly irregular rhythm, an abnormal heart sound (S1), chest pain, chronic shortness of breath, abnormal jugular venous pressure, fatigue, and impaired exercise tolerance. Other symptoms related to TIAs and strokes may be the initial symptoms of atrial fibrillation.

Some of the most common causes of atrial fibrillation are long-standing hypertension, congestive heart disease, cardiac valvular lesions, myocardial infarctions, history of coronary artery bypass grafts, hyperthyroidism, alcohol abuse, smoking, diabetes mellitus, and electrolyte imbalances.

13.2. AF, Normal, and Interference Recordings in ECG review screen and History List

All tracings analyzed as positive for atrial fibrillation, normal, or unreadable will have a tag for future review. These tags will be visible on the ECG History List as well as on the ECG review screen.

13.3. Activation of the Detectors

All Detectors, including AF, Normal, and Interference Detectors can be turned on or off in the settings of the *AliveECG* App.

14. MEDICATIONS

You can track your medications with the *AliveECG* app.

1. To access and edit the medications:
    - Tap “Insights” in the Menu at the bottom of the screen. Scroll to the bottom of the Insights screen and tap “Log Medications”. You can edit your medications or select those taken that day.
    - Alternatively, tap on the medication push notification that is sent to you by default at 9:00am every day. You can then edit your medications or select those taken that day.
    - You can also edit your medications by accessing your Profile. Tap “More”, “Profile”, “Medications”.
    - You can view medications selected on the Insights screen.
    - You can select a medication more than once per day by tapping “Medications Logged” at the bottom of the Insights screen, and tapping the specific medication again. The number to the right of the medication will update.

15. INSIGHTS

Your data will be graphed in the Insights section of the *AliveECG* App. To access it, tap the “Insights” icon in the menu at the bottom of the screen. The following items are graphed in Insights over a 7-day period, and over a 14-day period when the *AliveECG* app is turned to landscape view.

- Number of ECGs recorded, including the number of AF recordings and Normal Recordings.

- Heart rate (bpm) in each ECG recording, including those where AF and Normal were detected
- Symptoms and activities selected, including those where AF and Normal were detected
- Medications that were selected

NOTE: Your Insights are also available by logging into your account on www.alivecor.com. Insights data is available in 30-day increments, from when you first created your account. Note that this feature is available for individual users only, not for medical professionals.

16. ACCESSING HELP

Learn more about using your AliveCor Mobile ECG by tapping "More" in the lower right. Tap "HELP" to see all the options available.

- **Tutorials.** Review these tutorials to learn about to navigate all the features of the app
  - **Quick Tutorial**
  - **Recording an ECG**
  - **AF Detection**
  - **Sending for ECG analysis**
  - **Retrieving ECG analysis**
  - **Alternate positions**
- **Other Documentation.** Learn about ECG analysis; access the user manual, feedback and privacy and terms.
  - **What is ECG analysis**
  - **User Manual**
  - **Feedback**
  - **Privacy and terms**

17. EDITING USER PROFILE

- Launch the *AliveECG* app.
- Tap "More" in the lower right.
- Tap "Profile".
- All user details can be edited by tapping "Edit" in the upper right.

18. ACCESSING EDUCATION

- Launch the *AliveECG* app.
- Tap "More" in the lower right.
- Tap "Education". Users have the ability to learn about:
  - Cardiac Anatomy
  - What is an ECG
  - Arrhythmia Library
  - External Resources

NOTE: The information contained within this section is for educational purposes only. This information has been written and verified by medical professionals.

Do not attempt to use this information to interpret your own ECG. This information is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

19. PROVIDER DASHBOARD

The Provider Dashboard allows medical professionals the ability to view their patients' recordings automatically from their own account. To create a medical professional account, download the *AliveECG* app and follow the prompts to create a new account.

In order to view a patient's future recordings, you must send them an invite via email. To send an email invite:

1. Go to www.alivecor.com
2. Click on "SIGN IN" in the upper right corner and enter your email address and password
3. Click on "Invite a Patient"
4. Type in the patient's email address (this must be the email address they use for their AliveCor account)
5. Click "Send Email"

20. ELECTRONIC HEALTH RECORD (EHR) INTEGRATION

Send to EHR: If you are a physician and your AliveCor account has been setup for integration with an Electronic Health Record system (EHR) you can send ECG recordings to your EHR. You can see the option if you tap the bottom left corner of the review screen and choosing this option.

21. TROUBLESHOOTING

Problem	Solution
My Mobile ECG is not working.	If you're taking your first recording, please ensure that your Apple iPhone "Portrait Orientation Lock" is not on as you must be able to turn your phone to landscape orientation in order to take a recording. If you're using iOS 7 or greater, ensure that the *AliveECG* app has access to the iPhone microphone: 1. Tap on iPhone "Settings" 2. Tap on "Privacy" 3. Tap on "Microphone" 4. Ensure that "*AliveECG*" is turned on (the background of the slider is green) Change the battery 1. Expose the battery door at the back of the Mobile ECG: a. Remove the case from the smartphone or tablet by pushing the iPhone through the camera cutout, while peeling back the Mobile ECG from this corner. OR b. Remove the Mobile ECG from the attachment plate: 1. AC-001 - AC-007: Place your thumbs on the electrodes and press down firmly. Turn counterclockwise about 45 degrees to "unlock" the Mobile ECG. Once it's "unlocked", the Mobile ECG can then be lifted out of the plate. 2. AC-009: Use your thumbs to slide the Mobile ECG toward the open end of the plate. 2. Remove the battery door: a. AC-001 - AC-007: Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. b. AC-009: Insert a pen, pencil or other similarly shaped object into the cutout next to the battery door to pop the battery door off. 3. Remove the used battery and replace it with a new 3V coin cell battery matched to your model. 4. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable.

Problem	Solution
I have a lot of artifact, noise or interference in my recording.	Try the following tips for acquiring the best quality ECG recording: • Ensure that the “Enhanced Filter” is on. • Clean the electrodes on the Mobile ECG with alcohol-based sanitizer. • If hands are very dry, use a water-based lotion before recording. • When recording from the hands, relax the arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface and let the Mobile ECG rest on the hands. Do not squeeze the Mobile ECG. • Ensure that your smartphone or tablet is not charging/syncing and you are not using headphones with your smartphone or tablet during the recording. • Make sure that both the smartphone or tablet and the user remain still during ECG recordings. Movement during recordings will cause noise in the tracing. • Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the *AliveECG* app Settings. • Try recording from the chest, right under the pectoral muscle in the mid line.
The ECG rhythms appear upside down.	In the future, ensure that the left hand contacts the electrode closer to the top of the smartphone or tablet, and the right hand contacts the electrode closer to the bottom of the smartphone or tablet. To invert a recording on your smartphone or tablet, see “Invert the ECG recording” under “Recording Adjustments”.
I forgot my password and I’m unable to reset it.	To reset your password, go to www.alivecor.com and click on "SIGN IN" in the upper right corner and click on the "Forgot your password?" link below the Password field. On the Forgot Password screen, enter your email address and click Submit. Follow the reset instructions in the email. Please note the reset link contained in the email is only active for a short while.
I can’t see the login button	The Login button is only visible in portrait mode. If you have rotated your phone to landscape mode and can no longer see the login button, please rotate your phone to portrait mode. This will make the Login button visible so that you may login to the app.
The PDF Report looks slightly different on the Web and in my App	There is a 2.5 millisecond (thousandth of a second) difference in where the PDF starts for the Web Application and the Mobile Application. There is no difference in the recording and it will not impact how your ECG is interpreted.

Problem	Solution
My personal information (name, DOB, etc.) disappears when I'm trying to create an account.	If you navigate backwards when creating your account, the personal information you entered on the previous page is deleted and will have to be re-entered.
The HUD symbol is covered up when I rotate my phone.	The HUD symbol can sometimes be partially obstructed when you rotate your phone while it's busy. This isn't a concern; the HUD symbol is just letting you know that the app is working. This doesn't impact your recording or any of your information.
I see large spikes at the start of my recording	Large amounts of noise/artifact can be seen for the first few milliseconds of a recording when the Enhanced Filter is looking for your heartbeat. This is a very rare problem that lasts until your first heartbeat is seen in the app and doesn't affect the rest of your recording.
The real-time display of my ECG recording is lagging and jumps	If you are using an iPhone 4 and syncing a large amount of recordings from the server the real-time display of your ECG may be slow. This is an issue that has been reported for iPhone 4 and occurs after an update or after a new install of the application on a new phone. This does not impact the ECG recording itself. Waiting for sync to complete (can take up to 30 minutes) after re-installing the application will prevent this error from occurring.

22. ALIVECOR MOBILE ECG SPECIFICATIONS

Performance Characteristics

ECG Channel .....Single Channel
Input Dynamic Range.....10mV Peak-to-Peak
Memory length .....Practically Unlimited
Recording Format .....Continuous
Shelf Life .....Estimated 2 years

Circuitry

Frequency Response ..... 0.5 Hz to 40 Hz
CMRR..... 76 dB
Input Impedance ..... > 100 MOhm
Differential Range ..... +/- 5 mV
A/D Sampling Rate ..... 300 samples/second
Resolution ..... 16 bit
DC Offset Correction ..... +/- 300 mV

Output

Modulation .....Frequency Modulated Ultrasonic Audio Tone
Center Frequency .....19 kHz
Frequency Deviation ..... 200 Hz/mV

Power Requirements

Battery Type ..... 3V Coin Cell
Battery life ..... min. 200 Hours Operational Time, 12 months typical use

Physical Characteristics

AC-001 (for iPhone 4/4s) ..... 40 grams 118 x 62 x 15 mm 9 cm^2 Electrode
AC-003 (for iPhone 5/5s) ..... 41 grams 128 x 62 x 15 mm 9 cm^2 Electrode
AC-004 & AC-007-I5-A (for iPhone 5/5s)..... 33 grams 126 x 62 x 11 mm 10cm^2 Electrode
AC-004 & AC-007-UA-A (w/Attachment Plate). 28 grams 89 x 48 x 9 mm 10cm^2 Electrode
AC-009 .....18 grams 82 x 32 x 3.5 mm 9 cm^2 Electrode

Environmental Specifications

Operational Temperature ..... +10 to +45 degrees C
Operational Humidity .....10% to 95% (non-condensing)
Operational Altitude ..... based on your smartphone or tablet specification
Storage Temperature .....-20 to +60 degrees C
Storage Humidity .....10% to 95% (non-condensing)

User Interface

Two stainless-steel electrodes are exposed on the back of the Mobile ECG. These electrodes make contact with the user's skin.

23. EUROPEAN AUTHORIZED REPRESENTATIVE

Obelis SA

BD General Wahis 53

1030, Brussels

Belgium

Tel: +(32) 2. 732.59.54

Fax: +(32) 2.732.60.03

E-Mail: mail@obelis.net

24. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, Suite 600

San Francisco, CA 94108

United States

www.alivecor.com

25. ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions		
The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The AliveCor Mobile ECG uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AliveCor Mobile ECG is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AliveCor Mobile ECG requires continued operation during power mains interruptions, it is recommended that the AliveCor Mobile ECG be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE— U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">The AliveCor Mobile ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Mobile ECG should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the AliveCor Mobile ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = [\frac{3.5}{V_1}]\sqrt{P}$
$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]
Interference may occur in the vicinity of equipment marked with the following symbol:
 </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AliveCor Mobile ECG is used exceeds the applicable RF compliance level above, the AliveCor Mobile ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AliveCor Mobile ECG.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the AliveCor Mobile ECG			
The AliveCor Mobile ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AliveCor Mobile ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AliveCor Mobile ECG as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**80 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

26. SYMBOLS USED SYSTEM OR PACKAGE LABELING

	Type CF Applied Part
	European Conformity Mark
	WEEE – Properly Dispose of Electronic Waste
	Consult Instructions for Use / User Manual
	Manufacturer
	Temperature Limits (Operational)
	Relative Humidity Limits (Operational)
REF	**Model Number**
SN	**Serial Number**
	Direct Current Power Source